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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,363	11/15/2001	Richard C. Duke	3923-3	2524

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

11

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/991,363

Applicant(s)

DUKE ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This action is a Supplemental Restriction of the claims. Because the Examiner noticed that further restrictions were required in the claims which were overlooked in the prior action, this action is supplemental to the prior action, rather than a Notice of Non-Responsive Amendment.

However, it is noted that in the Response filed by the Applicant on April 11, 2003, the Applicant elected Group I with traverse. However, if the Applicant would look to pages 2, and 5-7 of the Restriction Requirement (reprinted below at, respectively, pages 3, and 4-5) the Applicant will note that election of Group I also requires the election of at least one subgroup, and a species as identified in those pages. As the Applicant made no such further elections, the Election is not fully responsive to the prior Office. The Applicant is requested to make such an election for the inventions of the elected Group of Groups I-IV. I.e. the Applicant is required to elect one of Groups I-IV, and of Groups A-C, and of Groups i-vii, and to a species as appropriate.

The additional material added to this restriction is the extension of the subgroup election requirement to Groups II-IV, rather than being required only where Group I is elected. These subgroups represent distinct inventions for the same reasons as indicated in the prior Restriction requirement with respect to the subgroups of Group I.

#### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1-15, drawn to therapeutic compositions comprising a dendritic cell, a yeast vehicle, and an antigen, classified in class 424, subclass 93.3.
- II. Claims 16-22, drawn to methods of making a therapeutic composition, classified in class 424, subclass 93.3.
- III. Claims 23-25, drawn to methods of eliciting an antigen-specific humoral response and an antigen-specific cell-mediated response by administering a composition comprising a dendritic cell, a yeast vehicle, and an antigen, classified in class 424, subclass 93.3.
- IV. Claims 26-28, drawn to methods of eliciting an antigen-specific humoral response and an antigen-specific cell-mediated response by administering a composition comprising a yeast vehicle and an antigen, classified in class 424, subclass 93.51.

For each of Groups I-IV above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-IV, and, election is also required to one of inventions A-C and to one of inventions i to viii. The subgroups A-C (represented by claims 4, 6, and 8, respectively, are linked by, e.g., claim 1) represent the inventions of the elected of Groups I-IV wherein:

- A- the yeast vehicle is loaded intracellularly with an antigen;
- B- the antigen is covalently or non-covalently attached to the yeast vehicle; or
- C- the yeast and the antigen are associated by mixing.

The subgroups i to viii (claim 9) represent the inventions of the elected of Groups I-IV wherein the antigen is:

- |                                  |  |
|----------------------------------|--|
| i, a viral antigen;              | ii, a mammalian cell surface molecule; |
| iii, a bacterial antigen;        | iv, a fungal antigen;                  |
| v, a protozoan antigen;          | vi, a helminth antigen;                |
| vii, an ectoparasite antigen; or | viii, a cancer antigen.                |

For Group II above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Groups I-IV, and, if (one of) Group II is elected, then election is also required to one of inventions IIA-IIID. These subgroups represent the method of Group II (claims 17, 18, 19, and 20, each linked by claim 16) wherein the yeast vehicle-antigen complex is formed by:

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- IIA- transfecting the yeast vehicle with a nucleic acid such that it expresses the antigen;
- IIB- loading the yeast vehicle with the antigen;
- IIC- mixing the yeast vehicle and the antigen; or
- IID- physically attaching the antigen to the yeast vehicle.

### ***Species Election***

3. This application contains claims directed to the several series of patentably distinct species of the claimed inventions described above.

The inventions of Groups I-IV each also require election of both the species of yeast used in the invention (claim 14- 9 species) and an election of the type of yeast vehicle used in the composition (claim 15- 5 species). Group I-i (therapeutic compositions with viral antigens) comprises 10 species.

Groups II and IIB each require election of the method of loading used with respect to the loading of the yeast with the antigen (claim 18-7 species) and the loading of dendritic cells with the yeast (claim 16-6 species)

The species are identified below.

For Groups I-IV, the applicant is required to elect one of the species identified as (a) to (e), and one of the species identified as (1) to (9).

The species of I-(a) to I-(e) represent the compositions of Group I wherein the yeast vehicles are selected from:

The species I-(i) to I-(ix) represent the inventions of Group I wherein the yeast vehicle is selected from the yeast genus:

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- |                                  |                              |
|----------------------------------|------------------------------|
| (a) whole yeast cells,           | (1) Saccharomyces,           |
| (b) yeast sphereoplasts,         | (2) Candida                  |
| (c) yeast cytoplasts,            | (3) Cryptococcus,            |
| (d) yeast ghosts, and            | (4) Hansenula,               |
| (e) subcellular yeast particles. | (5) Kluyveromyces,           |
|                                  | (6) Pichia,                  |
|                                  | (7) Rhodotorula,             |
|                                  | (8) Schizosaccharomyces, and |
|                                  | (9) Yarrowia.                |

For Group i, if elected, the applicant must elect a viral antigen to be examined. Thus, the applicant must elect one of the claimed compositions wherein the viral antigen is:

- |                          |                                 |
|--------------------------|---------------------------------|
| i-(a) HIV-1 gag,         | i-(b) HIV-1 env,                |
| i-(c) HIV-1 pol,         | i-(d) HIV-1 tat,                |
| i-(e) HIV-1 nef,         | i-(f) HbsAG,                    |
| i-(g) HbcAg,             | i-(h) hepatitis c core antigen, |
| i-(i) HPV E6 and E7, and | i-(j) HSV glycoprotein D.       |

For Group II, if elected, the applicant must elect one of the following species. These species represent the method of Group II wherein the yeast is loaded into the dendritic cell by:

- |                         |                          |
|-------------------------|--------------------------|
| II-(a) diffusion,       | II-(b) active transport, |
| II-(c) liposome fusion, | II-(d) electroporation,  |

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II-(e) phagocytosis, or

II-(f) bath sonication.

For Group IIB, if elected, the applicant must also elect one of the species IIB-(a) to IIB-(g).

These species represent the method of Group IIB wherein the antigen is loaded into the yeast by:

II-(a) diffusion,

II-(b) active transport,

II-(c) liposome fusion,

II-(d) electroporation,

II-(e) phagocytosis,

II-(f) freeze-thaw cycles, or

II-(g) bath sonication.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The generic claims are identified above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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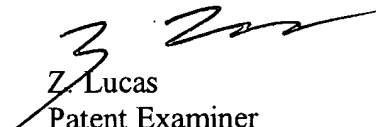
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
May 5, 2003

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
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5/19/03